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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,924	02/25/2004	Ben-Zion Dolitzky	1662/568078	9231

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Kenyon & Kenyon
One Broadway
New York, NY 10004

EXAMINER	
CHANG, CELIA C	
ART UNIT	PAPER NUMBER
1625	
MAIL DATE	DELIVERY MODE
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/788,924	DOLITZKY ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *4-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response filed on July 31, 2007 have been entered and considered carefully.

Claims 1-3, 14-16 are pending. Claims 4-13 stayed withdrawn form consideration.

2. The rejection of claims 1-3 under 35 USC 112 2nd paragraph is maintained for reason of record.

Applicants argued that "A person skilled in the art would readily understand that claim 1 is drawn to a crystalline form of fexofenadine hydrochloride characterized by the powder [power] X-ray diffraction(PXRD) peaks recited in the claim" on page 2 is *self conflicting* with applicants' own argument on page 4 wherein it was stated "As disclosed in page 12, lines 11-16, fexofenadine hydrochloride Form IX is a solvate of cyclohexane or MTBE". The ambiguity is self evidenced, which is the product of claim 1? Is it fexofenadine hydrochloride or is it fexofenadine hydrochloride cyclohexane solvate or is it fexofenadine hydrochloride MTBE solvate? Please note that in the chemical art fexofenadine hydrochloride, fexefenadine hydrochloride cyclohexane solvate and fexofenadine hydrochloride MTBE solvate are all *different chemical identities*. It has been clearly state by Seddon in the prior art reference recited on PTO-892 that "Now, as there should never be any doubt, *in this century*, about the chemical identity of a material, then it follows that solvates of a compound can never be pseudopolymorphs [of a compound], as there will never be any doubt as to their chemical identity". In addition, a material cannot be separated by ***all*** it's properties, applicants has not produced a material that has only fexofenadine hydrochloride *without the hexane or MTBE* that is crystalline and has the recited PXRD or any material that has only fexofenadine hydrochloride *without the hexane or MTBE* has the PXRD without the DTG profile.

The ambiguity as to "what" is claim 1 is self evident.

3. The rejection of claims 1-2 under 35 USC 102(b) over Ortyl et al. '872 is maintained for reason of record.

Applicants argued that by conversion of Ortyl's table 19, it appeared that there are different peaks in the instant PXRD and the Ortyl table.

Please note that on powder X-ray diffraction data, absent of side by side comparison, artifacts can suppress data to a single peak (Berstein p.118). The office has employed art recognized standard that *at least* one identical peak existed between the prior art and the instant claims, and seven was clearly identified in the previous office action. Please note that the claims are identical in chemical identity from the prior art, identical in seven peaks of the PXRD with understanding by the state of the art the differences being contributed by artifacts, anticipation was found. US pharmacopia clearly warned artisan in the field that minor difference does not confirm "polymorph" without careful factual evaluation. The mere allegation that they are different by attorney does not provide side by side comparison showing no artifacts in inter-laboratory data collection.

4. The rejection of claims 1-3, 14-16 under 35 USC 103(a) over Ortyl et al. '872 in ivew of Evans, US pharmacopia and Brittain supplemented with Gottlieb is maintained for reason of record.

In so far as the instant claims are concerned, the material of the claims, *fexofenadine hydrochloride crystal*, is identical to the Ortyl's material. The difference between the more limited claims and the process of employing a different solvent such as cyclohexane or MTBE, are routine choices by one having ordinary skill in the chemical art, thus, the inclusion of such impurity of solvents in the final product is nothing more than routine inclusion of Ortyl's product of minor impurity. Especially, attorney argued on pages 2-4 that the instant claims are not drawn to *different chemical identity* but the same "fexofenadine hydrochloride" as Ortyl's with different inclusion showing as different lines in XPRD. Impurities and results cause by impurities are within the sphere of invention as disclosed by prior art (see Evans). Applicants provided no evidence that why employing an alternative common laboratory solvent would not produce the same product with a little different impurity. Please note that the claims and the prior art are the *same identical material.*

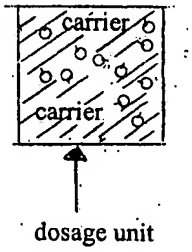
5. The rejection of claim 15 under 35 USC 112 first paragraph is maintained for reason of record.

It was clearly delineated with state-of-the-art references that the "predictable" result of pharmaceutical formulation is the formation of the thermodynamically stable form of any pharmaceutical material. On pages 22-24, the process of making the instant pharmaceutical composition which are routine formulation using processes such as liquid formulation, wet dispersion etc. for which clearly transforming of any crystalline form is *evidenced.*

That is:

Fexofenadine HCl form IX

Process of pages 22-24



carrier

Containing scattered material

Please note that any composition liquid or solid containing a "crystalline" form was neither described i.e. using what carrier; nor enabled, i.e. a composition containing the same X-ray diffraction pattern.

6. The rejection of claim 16 under 35 USC 102(b) over US 4,254,129 in view of Rowland et al. is maintained for reason of record.

Initially, applicants attention is drawn to applicants' argument on pages 2-4 of the response that the claimed "material" is the *identical* chemical compound fexofenadine hydrochloride as the prior art just of a different form. Even if the product contains impurity such as solvents, the process of treatment would be identical using identical material.

It was evidenced in the conventional teaching in the physiology of the human body that dissolution of the solvate can occur at several stages of drug kinetics (see p.23-24 specification). The first location is in the formulation stage wherein a liquid dosage such as injection ample, liquid capsule etc. was employed (see pages 23-24 specification), then the active ingredient being administer is the dissoluted compound fexofenadine hydrochloride.

In this scenario, anticipation is found since both the active ingredient and its out come is identical to the prior art.

The other location of dissolution can be expect at either the absorption and distribution stage (see Rowland and Tozer) or at the cellular level wherein receptor binding is occurring. Either stage of the claimed process would be a prima facie obvious modification of the prior art process employed by Carr et al. '129 because one skilled in the pharmaceutical art would expect *if the solvates had any different solubility or bioavailability,* the efficacy is slightly different from the non-solvated form, thus, the same process of use with an innate efficacy outcome. IN the instant case, *there is no description or evidence that any bioavailability issue was found in the specification*. Therefore, since after physiological deslvation, the same material and the same effect was the process evidence, anticipation was found.

Please note that applicants' argument with respect to PXRD peaks is irrelevant at the claimed process of physiological steps effecting receptor outcome.

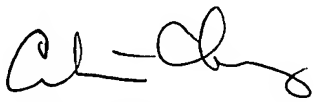
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



OACS/Chang
Oct. 24, 2007

Celia Chang
Primary Examiner
Art Unit 1625